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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,578	04/29/2002	L.Brian Starling	4141-2-PUS	9225

22442 7590 10/18/2005

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EXAMINER	
DAVIS, RUTH A	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 10/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/030,578	STARLING ET AL.	
	Examiner	Art Unit	
	Ruth A. Davis	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 July 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) *15-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *07252005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment and response field July 25, 2005 has been received and entered into the case. Claims 1 – 43 are pending; claims 15 – 43 are withdrawn from consideration; claims 1 – 14 have been considered on the merits. All arguments have been full considered.

Claim Rejections - 35 USC § 112

1. Rejections under 35 U.S.C. 112, second paragraph, have been withdrawn due to amendment.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1 – 3 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Radin in view of Lemons, Day et al. (US 6358531 B1) and/or Inoue et al. (US 4798585 A).

Applicant claims a composition comprising hollow sintered calcium containing microstructures and a bone mixture; wherein the microstructures are about 0.5 – 6 mm in diameter and the bone mixture comprises bone tissue or bone by products. The calcium containing microstructure comprises hydroxyapatite, tribasic calcium phosphate, dicalcium phosphate, tetracalcium phosphate, calcium carbonate, calcium oxide, glass containing calcium phosphate or a mixture thereof.

Radin teaches compositions comprising hollow calcium phosphate containing glass shells (abstract) that are combined with biologically active molecules such as BMP or collagen (bone mixture, tissues or by-products) (p.8). The particles vary in size from about 50 mcm – 5 mm (p.6).

Radin does not teach the compositions wherein the calcium phosphate is sintered. However, at the time of the claimed invention, sintered calcium phosphate was a known and used material in composition that contain calcium shells, implants, and structures. In support, Lemons teaches calcium particles wherein the particles are made from sintered tricalcium phosphate (tribasic calcium phosphate) and/or hydroxylapatite (abstract, col.8 line 65- col.9 line 5), Day teaches porous, hollow calcium shells that can be sintered (col.6 line 15-30), and Inoue teaches calcium implants wherein the calcium phosphate materials are sintered (abstract). As

evidenced by the cited references, it was well known and practiced in the art to sinter calcium containing microstructures. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice and the cited references to sinter the hollow calcium structures of Radin with a reasonable expectation for successfully obtaining the hollow calcium shell of Radin.

5. Claims 1 – 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Radin in view of Lemons, and further in view of Day and/or Inoue.

Applicant claims a composition comprising hollow sinteredcalcium containing microstructures and a bone mixture; wherein the microstructures are about 0.5 – 6 mm in diameter; and the bone mixture comprises bone tissue or bone by products at about 5 – 95% or 50 – 75% of the composition. The calcium containing microstructure comprises hydroxyapatite, tribasic calcium phosphate, dicalcium phosphate, tetracalcium phosphate, calcium carbonate, calcium oxide, glass containing calcium phosphate or a mixture thereof.

Radin teaches compositions comprising hollow calcium phosphate containing glass shells (abstract) that are combined with biologically active molecules such as BMP or collagen (bone mixture, tissues or by-products) (p.8). The particles vary in size from about 50 mcm – 5 mm (p.6).

Radin does not teach the compositions wherein the calcium phosphate is sintered. However, at the time of the claimed invention, sintered calcium phosphate was a known and used material in composition that contain calcium shells, implants, and structures. In support,

Lemons teaches calcium particles wherein the particles are made from sintered tricalcium phosphate (tribasic calcium phosphate) and/or hydroxylapatite (abstract, col.8 line 65- col.9 line 5), Day teaches porous, hollow calcium shells that can be sintered (col.6 line 15-30), and Inoue teaches calcium implants wherein the calcium phosphate materials are sintered (abstract). As evidenced by the cited references, it was well known and practiced in the art to sinter calcium containing microstructures. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice and the cited references to sinter the hollow calcium structures of Radin with a reasonable expectation for successfully obtaining the hollow calcium shell of Radin.

Radin does not teach the compositions comprising the claimed amounts of bone mixture. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize the amounts of such active ingredients as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the amounts of biologically active molecules in the compositions of Radin with a reasonable expectation for successfully obtaining the calcium shell of Radin. Furthermore, although Radin does not teach the microstructures comprising each of the claimed calcium materials, it would have been obvious to one of ordinary skill in the art o use any of the claimed materials since they were routinely used in such compositions. In support Lemons teaches compositions comprising calcium particles wherein the particles are made from sintered tricalcium phosphate (tribasic calcium phosphate) and/or hydroxylapatite (abstract, col.8 line 65- col.9 line 5). Thus, such materials were well known in the art to be equivalent substitutes used for the same purpose. Moreover, at the time of

the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to substitute any of the claimed calcium containing materials in the composition of Radin with a reasonable expectation for successfully obtaining an effective calcium shell.

6. Claims 1 – 3 and 7 – 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Radin in view of Lemons, Day and/or Inoue, and further in view of Gerhart.

Applicant claims a composition comprising hollow calcium containing microstructures and a bone mixture; wherein the microstructures are about 0.5 – 6 mm in diameter; and the bone mixture comprises bone tissue or bone by products. The calcium containing microstructure comprises hydroxyapatite, tribasic calcium phosphate, dicalcium phosphate, tetracalcium phosphate, calcium carbonate, calcium oxide, glass containing calcium phosphate or a mixture thereof. The composition further comprises a bonding agent that is a polymer selected from polyactic acid, polyglycolic acid, polycaprolactone, poly alpha hydroxyl esters, polyphosphatzenes, polyanhydrides and/or polypropylene fumarate; or a bonding agent is a calcium containing cement. The bonding agent is present at about 5 – 75% or 10 – 50% of the composition. The calcium containing cement is calcium phosphate, calcium sulfate or a mixture thereof, specifically calcium sulfate.

Radin teaches compositions comprising hollow calcium phosphate containing glass shells (abstract) that are combined with biologically active molecules such as BMP or collagen (bone mixture, tissues or by-products) (p.8). The particles vary in size from about 50 mcm – 5 mm (p.6).

Radin does not teach the compositions wherein the calcium phosphate is sintered. However, at the time of the claimed invention, sintered calcium phosphate was a known and used material in composition that contain calcium shells, implants, and structures. In support, Lemons teaches calcium particles wherein the particles are made from sintered tricalcium phosphate (tribasic calcium phosphate) and/or hydroxylapatite (abstract, col.8 line 65- col.9 line 5), Day teaches porous, hollow calcium shells that can be sintered (col.6 line 15-30), and Inoue teaches calcium implants wherein the calcium phosphate materials are sintered (abstract). As evidenced by the cited references, it was well known and practiced in the art to sinter calcium containing microstructures. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice and the cited references to sinter the hollow calcium structures of Radin with a reasonable expectation for successfully obtaining the hollow calcium shell of Radin.

Radin does not teach the composition further comprising a bonding agent that is one of the claimed polymers or calcium containing cements, or wherein the cement is present at the claimed amounts. However Radin specifically teaches that the hollow particle compositions are used for filling or repairing bone defects (p.4,9). Gerhart teaches that cements are well known and commonly used in compositions for repairing and fixing bone defects (col.1 line 10-36). Gerhart also teaches compositions for bone repair/fixation comprising calcium phosphate particles combined with a cement composition (or bonding agent) and calcium salts. Specifically, Gerhart teaches that the calcium particles are incorporated with polymers, allowing for superior fixation (col.2 line 22-35). The polymers used include polyesters, polyanhydrides, and/or polypropylene fumarate (col.4 line 35-52, col.5 line 1-8). Gerhart additionally teaches

that the cement compositions comprise calcium sulfate or calcium phosphate (col.6 line 40-52). At the time of the claimed invention, one of ordinary skill in the art would have been motivated by the teachings of Gerhart to include the claimed cements or polymers as a bonding agent in the composition of Radin, for its known use in bone repair compositions, and its advantage of superior fixation as disclosed by Gerhart. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Gerhart to include any of the claimed cements or polymers in the compositions of Radin with a reasonable expectation for successfully obtaining the calcium shell composition of Radin.

While the references do not teach the claimed amounts of cement, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize the amounts of such active ingredients as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the amount of cement with a reasonable expectation for successfully obtaining the composition obtained by the combined teachings of Radin and Gerhart.

Double Patenting

7. Rejections under the judicially created doctrine of obviousness-type double patenting have been withdrawn due to amendment.

Response to Arguments

Applicant argues that the references do not teach hollow, sintered calcium materials.

However, this argument fails to persuade in light of the rejections made above. Specifically, the supporting references teach that sintered calcium materials were known and well used in the art for hollow calcium containing structures and compositions made therefrom. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice and the cited references to use sintered calcium in the hollow compositions of the prior art with a reasonable expectation for successfully obtaining the hollow microstructures disclosed therein.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ruth A. Davis
October 11, 2005
AU 1651

LEON B. LANKFORD JR.
PRIMARY EXAMINER